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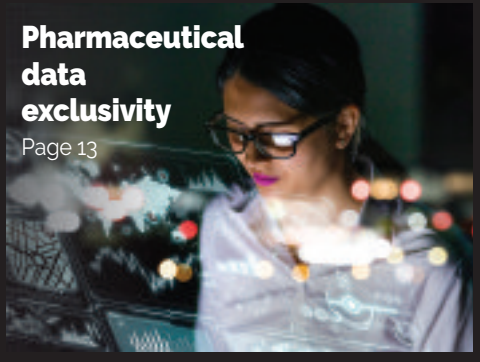
# Data as a critical asset in the health sector

Laurie-Anne Ancenys and Juliette Olliveaud of Allen & Overy examine the challenges posed to patients and healthcare providers by an increasing volume of data



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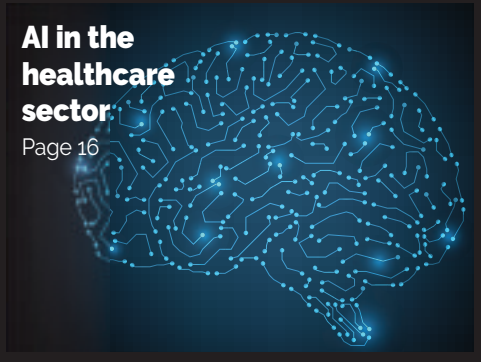

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# COVID-19: The invisible enemy revisited

**Alejandro Luna Fandiño of Olivares looks at Mexico's response to the ongoing Coronavirus pandemic.**

In 2009, Mexico battled the first pandemic of the 21st century. An outbreak of a new strain of influenza, the AH1N1 disease emerged, known at the beginning as the "swine flu" or with the xenophobic name of "Mexican flu". The outbreak was believed to have originated in Mexico and was first identified in the country in March. Shortly after its identification, the Mexican government acted quickly to impose tight measures across the country. Millions of face masks were handed out to citizens by the military and police forces. Schools, libraries, museums, concerts, and other public gathering venues were shut down and Mexico City carried out a 15-day quarantine.

Before the pandemic emerged, there were already two available and patented antiviral drugs indicated for influenza, TAMIFLU® (OSELTAMIVIR) and RELENZA® (ZANAMIVIR), which were already on the market. In 2009, these were found to have a significant effect on reducing the severity and duration of the AH1N1 disease symptoms. Many countries agreed that these drugs were useful in the treatment and prevention of the AH1N1 disease. Their immediate availability, together with the Mexican government's quick response, are believed to have helped control the spread of the virus in Mexico.

Eleven years later, the world has found itself in the midst of another global pandemic. COVID-19 has spread across countries rapidly and in a seemingly uncontrolled manner. The majority of nations have responded by ordering some form of lockdown, with varying levels of enforcement.

COVID-19, contrary to AH1N1, is understood to be a coronavirus, rather than a strain of influenza. For this reason, we still know relatively little about the disease and although a vaccine is currently in the early stages of clinical trials; to date, no treatment has been identified and universally agreed-upon.

At the moment of writing this article, compared to other countries, the number of confirmed cases of COVID-19 in Mexico are relatively low. However, trends may suggest that we are at the beginning of an upward curve. There are concerns that Mexico's healthcare infrastructure would not be able to cope with an exponential increase in case numbers and the Mexican Government issued already a declaratory of COVID-19 as a disease of priority attention which is the first step for an eventual or potential declaratory of emergency and then, compulsory licenses.

Alejandro Luna Fandiño

> **"COVID-19 has spread across countries rapidly and in a seemingly uncontrolled manner."**

On 23 March 2020, the Mexican Patent and Trademark Office (IMPI) issued a decree suspending and interrupting procedural terms from 24 March to 19 April 2020. The suspension of activities does not apply to those procedures which are necessary to mitigate the consequences of the pandemic.

On 24 March, the Mexican President announced that Mexico officially entered phase 2 (local transmission) of the outbreak of COVID-19. New and additional measures to contain the spread of COVID-19 and "flatten the curve" of transmission were announced.

These measures were taken gradually by several public and private entities. It is highlighted that most of the private sector acted earlier, faster and in a stricter manner when compared with the public sector.

On 26 March, the Ministry of Health issued a decree suspending the legal terms running during the period of 26 March to 19 April, due to *force majeure*.

The Ministry of Health specified that all of its dependencies would provide everything necessary so that the necessary personnel continue to work to carry out all the procedures that are essential and/or urgent to deal with the contingency, in order to assure the continuity of operations of


## Résumé

**Alejandro Luna Fandiño**

Alejandro Luna co-chairs OLIVARES' Life Sciences & Pharmaceutical Law industry group and coordinates the Litigation Department. As one of the country's few patent and regulatory experts, he has led efforts to update Mexico's IP system in order to best serve his clients and is ranked highly by leading IP industry publications.

essential functions related to the control of the COVID-19 virus pandemic.

Sanitary authorizations related to medicines, medical devices and import of supplies, among others, that are strictly related to the attention of the COVID-19 pandemic, will continue to be processed by COFEPRIS during said period.

COFEPRIS announced that their Comprehensive Services Center (CIS) will also remain open to receive and attend to those procedures that are required in order to continue with the supply of medical products to respond to the general health needs of the population (not necessarily related to COVID-19).

At the time of writing this article, it is expected that the Mexican Patent Office (IMPI) will extend the period of inactivity until 5 May, however confirming that new applications for patents, trademarks and designs can be made on-line.

On March 27, the Mexican President published a Decree in the Federal Gazette, implementing extraordinary measures in relation to the outbreak of COVID-19.

This Decree announced the following extraordinary and immediate measures:

- The use of all medical resources available in the public and private sectors in the regions and the surrounding areas.
- The acquisition of all types of goods and services, at national or international level, such as medical equipment, diagnostic agents, surgical and healing materials and hygiene products, as well as any other type of good or service, without any public tender procedure, for the quantities or concepts that are necessary to face the contingency.
- The import and authorization of imports of the above-mentioned goods and services with minimal or no administrative procedure requirements, for the required quantities or concepts.
- Taking the corresponding measures in order to avoid price speculation and stockpiling of the essential products mentioned above.
- Any other measure that is considered necessary by the Ministry of Health.

The Mexican sanitary regulatory agency, COFEPRIS, published an announcement on its official website stating the petitions and proceedings that will remain open during this phase 2 of the pandemic in Mexico. The notice includes applications for "products" that may be used to overcome the health emergency of COVID-19.

## Mexico Declares State of Emergency

On 31 March, due to the increase in cases of contagion, the Secretary of Health published a Decree issued by the Health Counsel in the Official Gazette of the Federation, establishing extraordinary actions to address the health emergency due to causes of force majeure, generated by the SARS-CoV2 virus (COVID-19).

There are many doubts and questions regarding the definition or scope of some of the measures and concepts established in this decree, especially the concepts of "emergency due to causes of force majeure", instead of a "contingency or health emergency"; similarly, many questions have arisen about the definition of "essential activities".

Needless to say, the highlighted controversial concepts, as well as all the measures, will have a series of legal impacts on the regulatory, administrative, labor, contractual, and tax fields, among others.

When finalizing this article, it seems that the measures will be extended until June, and the peak of contagious in Mexico will be mid-May.

## COVID-19 treatments and patents

Certain pharmaceutical products currently indicated and marketed for other therapeutic indications have shown efficacy in the treatment of the COVID-19 disease. Some of these are already being used as treatments for COVID-19 in other countries. For example, early evidence showed that REMDESIVIR, which was tried on only a few patients in Wuhan, seemed to work well; CLOROQUINE, a treatment for malaria, seemed to be useful for the treatment of serious pneumonias; and LOPINAVIR, a treatment for HIV, and FAVIPIRAVIR had also shown positive results.

The Mexican sanitary regulatory agency, COFEPRIS, has already approved clinical trials for four of the pharmaceutical products that have shown usefulness in the treatment of COVID-19. These are REMDESIVIR, TOCILIZUMAB, HYDROXYCHLOROQUINE and CHLOROQUINE & AZITHROMYCIN. Some of these pharmaceutical products are currently protected by patents and are already being marketed and sold to the general public for other therapeutic indications. Others are in the process of obtaining patent protection.

Patents provide the titleholder with the exclusive right to make, use or sell the product. If a third-party company tries to make, use, or sell a product protected by a patent, the titleholder has the right to commence infringement proceedings before the Mexican Patent Office, IMPI, and later, the courts. During the proceedings, IMPI and/or the courts will decide whether there is actual infringement of the patent. If the court decides that there is actual infringement, a subsequent court procedure will determine the amount of damages the third-party company must pay to the titleholder. This process is very lengthy and expensive for both the titleholder and the third-party company.

During pandemics, patents might seem inequitable and a barrier to public health; this is not necessarily genuine. Once a medicine is approved for the treatment of the COVID-19 disease, it will need to be quickly produced and distributed across the country in an enormous scale. Because only the titleholder (and any commercial licensees) have the right to make and sell the medicine, thus, in case of a global pandemic, third-party pharmaceutical companies would be deterred from meeting an eventual shortage.

## Compulsory license regulations in Mexico

The Mexican Industrial Property Law provides for the grant of compulsory licenses in the event of a national emergency, such as a serious disease as declared by the General Health Council. This law helps protect against the risk that patent protection will hinder the production and/or supply of drugs in the event of a health crisis.

The grant of a compulsory license is not automatic. The declaration of serious illness is the first phase of the procedure of the grant of compulsory licenses. According to Article 77 of the Industrial Property Law and Article 51 of its Regulations, the following procedure inter alia must be followed for the grant of a compulsory license:

- There must be a risk that the lack of a compulsory license would prevent, hinder, or increase the price of the supply, distribution, or access to the patented product.
- The General Health Council must issue a declaration of emergency in the Official Gazette, justifying priority attention for the serious disease.
- Once the declaration of emergency is published, third party pharmaceutical companies can request a compulsory license from the Mexican Patent Office (IMPI).
- IMPI will decide whether to grant the compulsory license within a term of no longer than 90 days from the date of the petition.
- Through an agreement with the Secretary of Economy, IMPI may decide to grant the license and, if so, publish a declaration stating that the exploitation of certain patents may be carried out by the grant of a license for the public benefit.
- Within two months after the publication the declaration, the affected patent holders have an opportunity to protest it
- Once the protests have been heard, IMPI will make a definitive resolution, confirming or revoking the declaration.
- Subject to successful challenge by the affected patentee to the grant of license and the declaration being upheld by IMPI, the Ministry of Health will establish the production conditions, quality controls, duration, and scope of application of the license.
- IMPI will determine the appropriate royalties the licensee is to pay the patent holder, upon hearing submissions from both parties.
- The compulsory license is neither exclusive nor transferrable and will be in effect for as long as the public health emergency requires.

AH1N1 in 2009 and COVID-19 now

The 2009 AH1N1 crisis was the first time Mexico came very close to granting compulsory licenses for reasons of national emergency for the public benefit. The disease had spread rapidly to over 200 countries, and the World Health Organization declared a pandemic. At that time, there were already two available treatments for the AH1N1 disease, which were both protected by patents.

However, the requirements for compulsory licenses were not met, which meant that they were not granted. There was no evidence to suggest that the titleholders of the patents for TAMIFLU® and RELENZA® were unable to supply to drugs in a sufficient quantity or that there was a national shortage of supply. There was also no evidence that prices had been set high, on the contrary, it has been said that a pandemic price was agreed between the Mexican government and the titleholders, neither there was evidence that distribution was being blocked.

In any case, the General Health Council had not published a declaration of emergency in the Official Gazette, which is the first phase of the procedure for the grant of compulsory licenses.

In comparison, the COVID-19 pandemic seems much more serious and advanced. When the AH1N1 disease emerged, scientists already knew a lot about influenza through centuries of humans battling mild and severe strains and through decades of research. They comparatively know much less about the new and coronavirus, including its transmission and mortality rate, because it has not been studied as extensively.

Like the AH1N1 virus, the COVID-19 disease has also been declared a pandemic by the World Health Organization and has spread to 185 countries so far. However, the Mexican government's response, at least at the moment of writing this article, appears much more gradual and less strict than it was in 2009, which could be impacting the disease's transmission. It is also impactful that there is currently no universally accepted treatment or cure. Clinical trials are currently underway in Mexico, but it will take time to be approved and then produced and distributed to the general public on a large scale. While a vaccine is currently in development, it would also have to go through rigorous clinical trials to ensure its safety and efficacy, leading some to predict that it could still be a year away from general public use.

## Conclusion

There has been no precedent for a compulsory license being granted in Mexico, despite coming close during the pandemic of the AH1N1 disease. There were also other mechanisms that were used in 2009 that avoided the need or the legal scenarios for the issuance of compulsory licenses, such as free licenses, cooperation of the authority and titleholders, patents dedicated to the public and pandemic pricing.

In any case, if there is evidence of a shortage of supply or unfair pricing that could limit availability of the medicine and damage the health of the population, compulsory licenses are intended as a safety net to ensure that titleholders are not risking lives for reasons of mere exclusive rights. Provided the conditions in TRIPS and NAFTA and reproduced in the Mexican Industrial Property Law are met, there is no legal reason why they would not be granted but conditions provided and processes contained therein should be observed, otherwise the act would be dictatorial.

If a universal treatment for COVID-19 does become available and if it is patent-protected, the hope is that, similarly, such treatment will not be in short supply and therefore the conditions for compulsory licenses will not be met. This is not only a legal prediction but also a real desire, because if the conditions are not met, this would indicate that the outbreak is not so dangerous and damaging to public health or that we, as human kind, through the health measures and cooperation, defeated the invisible enemy.

Whether the current circumstances will lead to a different result under the provisions of the Mexican compulsory license provisions merits close attention. Nevertheless, whether compulsory licenses are required for this pandemic, history has taught us that a fast-acting government and responsible citizens working in solidarity can help to control the transmission of this invisible enemy.


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